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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/774,299 | 02/06/2004 | Brian Cox | 388700-612-05-CIP2 | 5453 |

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INSKEEP INTELLECTUAL PROPERTY GROUP, INC
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| EXAMINER |
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MASHACK, MARK F

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| ART UNIT | PAPER NUMBER |
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3773

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01/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

inskeepstaff@inskeplaw.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/774,299 | COX ET AL. | |
| | Examiner | Art Unit | |
| | MARK MASHACK | 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17, 19-22 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 10/29/2010. Claims 1-17, 19-28 are pending. Claims 1-12 have been withdrawn.

Response to Arguments

1. **Regarding Claims 13-17, 19-24**, Applicant's arguments filed 1/29/2010 have been fully considered but they are not persuasive. Applicant argues that "Examiner Masha[c]k indicated that [the 103 rejections] would be withdrawn". Examiner disagrees. No agreement was reached in the interview dated 9/24/2010.
2. Applicant's arguments with respect to **Claims 25-28** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. **Claims 25-28** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claims 25** recites the limitation "purging air from the lumen... reducing friction... prior to introducing the device into a patient". The hydrophilic, softening coupling element is disclosed in one embodiment (Paragraphs 55,

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58 and Figs 3-4) and the purging air prior to introducing the device in to a patient is disclosed in a separate embodiment (Paragraphs 64-68 and Figs 11-17). There is no disclosure to combine the embodiments. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claim 13, 17, 19-21** is rejected under 35 U.S.C. 103(a) as being unpatentable **Rosenbluth et al. ("Rosenbluth" US 6,015,424)** in view of **Naglireiter (US 6,514,264)**.

Regarding Claim 13, Rosenbluth discloses a method comprising providing an elongate, flexible, hollow deployment tube **16**; providing a filamentous endovascular device **12, 50** with a proximal end and the device **50** is provided with a coupling element (the distal end) formed with purge passage **62**; introducing the endovascular device

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intravascularly to the target site; and separating the endosvascular device from the deployment tube (Column 6, Lines 31-54, Column 6, Line 64, - Column 7, Line 8, Column 7, Lines 29-50). Examiner asserts that **Rosenbluth** does not disclose of any radially expansion of the deployment tube during the separating step. **Rosenbluth** does not explicitly disclose of the purging step. However, **Naglireiter** teaches of purging the lumen of air through a purge passage prior to introducing the device (Column 5, Lines 43-53). Given the teachings of **Naglireiter** it would have been obvious either embodiment of **Rosenbluth** modify the method by purging air from the coil in order to prevent introducing air into the vasculature. **Regarding Claim 17, Rosenbluth** discloses of the deployment tube comprising a retention sleeve **24** at a distal end thereof such that said coupling element is releasably held by said retention sleeve. **Regarding Claim 19**, the injected liquid would apply pressure directly to the coupling element. **Regarding Claim 20**, the purge passage is formed in the exterior surface of the coupling element. **Regarding Claim 21**, when saline is injected, the trapped air passes "through passageway **126** and then out of the system" (**Naglireiter Col 5, Lines 47-48**), which requires the air to pass through the helical grooves of the coil; therefore the helical grooves of the coil can be considered a portion of the purge passage.

8. **Claims 14 and 22-24** rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenbluth** in view of **Naglireiter** as applied to Claim 13 in further view of **Eder (US 6,063,070)**.

Rosenbluth in view of **Naglireiter** disclose all of the claimed limitations as disclosed above except for the steps of: (f) generating an electrical signal in response to the separation of the endovascular device from the deployment tube. However, **Eder** teaches of deployed an indicator circuit to monitor the progression of the coil detachment (Column 3, Lines 18-27). The coil would inherently be a component of the circuit and when the detachment of the coil would alter the circuit in some manner. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Eder**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of by generating an electrical signal in response of the separation of the endovascular device from the deployment tube. Doing so would provide feedback to the user of the separation.

9. **Claims 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenbluth** in view of **Naglireiter** as applied to Claim 13 in further view of **Ressemann et al.** ("**Ressemann**" US 6,224,609).

Rosenbluth in view of **Naglireiter** disclose all of the claimed limitations as stated above including the purge passage being dimensioned so as to provide a substantial restriction to the flow therethrough of a liquid having a viscosity greater than or equal to a predetermined viscosity. However, **Rosenbluth** in view of **Naglireiter** does not

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explicitly disclose the use of a contrast agent. However, **Ressemann** discloses that it is commonly known in the art to use a combination of saline and a contrast agent in order to visualize an area in the vasculature (Column 8, Lines 16-18). Examiner asserts that providing the endovascular device in the catheter would inherently provide a substantial restriction that the combination of saline and contrast medium would have a viscosity of "at least *about* 2cP". All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Ressemann**, it would have been obvious to provide a contrast agent with the saline of **Rosenbluth** in view of **Naglireiter** to provide assist in the tracking and visualization of the deployment device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773